## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Foshan Flying Medical Products Co., Ltd.

Model Tested: KFT-02 Date Tested: May 7, 2020

These findings pertain to the Foshan Flying Medical Products Co., Ltd., model KFT-02. The labeling for these respirators indicate they meet GB19083-2010 (the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use).

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found here.

The maximum and minimum filter efficiency was 97.98% and 96.88%, respectively. All ten respirators measured more than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. Therefore, even though the filter efficiency measured was more than 95%, users need to ensure a proper fit is achieved.

This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirator's represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for <u>Crisis Capacity Strategies (during known shortages)</u>.

## **Evaluation of International Respirators**



**Test:** Modified TEB-APR-STP-0059

Date Tested: May 7, 2020

Report Prepared: May 8, 2020

Manufacturer: Foshan Flying Medical Products Co., Ltd.

Item Tested: KFT-02

Country of Certification: China (Chinese Standard GB19083-2010)

Pictures have been added to the end of this report.

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	10.9	2.51	2.51	97.49
2	85	11.6	2.35	2.35	97.65
3	85	11.4	3.00	3.00	97.00
4	85	11.3	2.60	2.60	97.40
5	85	10.9	2.92	2.92	97.08
6	85	12.1	3.12	3.12	96.88
7	85	11.9	2.13	2.13	97.87
8	85	12.1	2.37	2.37	97.63
9	85	12.5	2.02	2.02	97.98
10	85	12.0	2.12	2.12	97.88
Minimum Filter Efficiency: 96.88			Maximum Filter Efficiency: 97.98		

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control
  over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.



## N95 Respirator Disposable Mask User Guide

- Wash your hands well before putting on your mask.
- Unfold the mask. Cup the mask in one hand and place it over your mouth and nose. Place the mask in the palm of your hand so that the straps face the floor. Set it over your nose and mouth with the nosepiece fitting over the bridge of your nose. The bottom should go just under your chin.



- Pull the bottom and top straps over your head. The elastic ear loop should fit behind your ears.
- 4. Mold the nose piece around the bridge of your nose. Set your first 2 fingertips on either side of the metal nose clip at the top of your mask. Run your fingers down both sides of the strip, molding it along the bridge of your nose.

- 5. Checking the seal. Breathe through the mask and test for leaks. Set both hands against the mask and take a breath to make sure that it seals against your face. Then exhale, feeling for any leakage from the nosepiece or around the edges. If you feel air leaking from the nose area, re-mold the nosepiece. If it's coming from the edges of the mask, adjust the placement of the straps on the sides of your head.
- Removing the mask. Without touching the front of the mask, pull the either side of the ear loop off, hold only the ear loop of the mask to throw it away.



Warning: Talk to your doctor before using if you have any of the following conditions:

- Breathing problems
- Emphysema
- Chronic obstructive pulmonary disease (COPD)
- Asthma
- Cardio-pulmonary
- Immune compromised medical condition problems

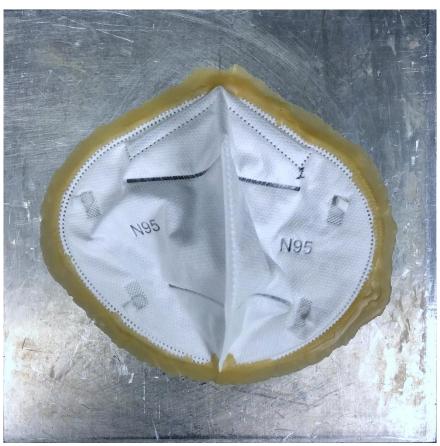
Non-medical use





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